UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

LAVETA JORDAN, *et al*., Plaintiffs	)	
vs.	)	CIVIL ACTION NO. 4:17-CV-00865-CEJ
BAYER CORPORATION, *et al*., Defendants	)	

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AMENDED PETITION FOR DAMAGES

COME NOW the above named Plaintiffs, by and through their undersigned counsel, and file their Amended Petition for Damages against BAYER CORPORATION, BAYER HEALTHCARE LLC., BAYER ESSURE, INC., (f/k/a CONCEPTUS, INC.), and BAYER HEALTHCARE PHARMACEUTICALS, INC., (collectively herein referred to as "Bayer" or "Conceptus" or the "Bayer Defendants"), incorporate by reference Plaintiffs' Petition For Damages, filed January 19, 2017, and amend section **III. JURISDICTION AND VENUE** as follows:

III. JURISDICTION AND VENUE

167. This Court has personal jurisdiction, pursuant to § 506.500 R.S. Mo., over the Defendants because at all relevant times they have engaged in substantial business activities in the State of Missouri.

168. Further, at all relevant times, the Defendants transacted, solicited, and conducted business in Missouri through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Missouri, and committed torts in whole or in part against Plaintiffs in Missouri.

169. There is "specific" personal jurisdiction, because Defendants used St. Louis, Missouri, to develop, create a marketing strategy for, label, or work on the regulatory approval, for Essure®, and all of the Plaintiffs' claims arise out of or relate to the Defendants' contacts with Missouri.

170. There is an affiliation between Missouri and the underlying controversy alleged in this Complaint, principally, activities and/or occurrences that took place in Missouri, and the Defendants are therefore subject to Missouri's regulation.

A. Defendants engaged in extensive contacts with Missouri during the development of Essure®, creating a marketing strategy for Essure®, creating the Essure® labeling, and in obtaining FDA approval of Essure®.

B. St. Louis, Missouri was a site of the studies that allowed Conceptus to clear Essure® for marketing with the FDA and thereafter to continue marketing the product with inadequate labeling because of a failure to follow-up during post-marketing testing.

C. Conceptus was required to conduct four pre-approval clinical studies for Essure®'s initial pre-market approval ("PMA") submission to the FDA. To the best of Plaintiffs' knowledge, for three of those four pre-market clinical studies for Essure®, Conceptus used Missouri hospitals and contracted with Missouri physicians to serve as clinical investigators.[1] Specifically, Conceptus chose Missouri to conduct: **(1) Phase**

[1] Pursuant to 21 CFR 812.43(a), it was Conceptus' responsibility as sponsor, to select the clinical investigators who are "qualified by training and experience" to investigate the device. Conceptus was also required to maintain control over its investigational materials and monitor the study in accordance with 21 CRF 812.46. The study investigator uses his or her patient population to screen study participation, is responsible for patient enrollment and patient medical care, and more importantly, is responsible for the assessment, recording and reporting of adverse events. *See* 21 CFR 812.3 (4)(i); 21 CFR 812.100; 21 CRF 812.110; 21 CRF 812.140.

1A/STOP 01—STOP Device[2] Placement Feasibility Study Using Hysteroscopy Visualization ("STOP 01 Study"); **(2) Phase 1B/STOP 06**–Evaluation of the Safety and Principles of Operations of the Selective Tubal Occlusion Procedure (STOP) Device in Women Who Are Scheduled To Undergo A Hysterectomy ("STOP 06 Study"); and **(3) Phase III Pivotal (STOP 2000)**— Phase III Study – A Multi-Center Clinical Trial to Demonstrate the Safety and Effectiveness of the STOP Device in Providing Permanent Contraception (hereafter "Pivotal Study").[3]

D. To conduct the **STOP 01** and **STOP 06** studies, Conceptus contracted with Richard Gimpelson, M.D., clinical professor at the St. Louis University School of Medicine, Department of Obstetrics and Gynecology, and staff at, among others, St. John's Mercy Medical Center in St. Louis, Missouri and St. Luke's Hospital, Chesterfield, Missouri, to serve as the Co-Principal investigator.[4] According to the FDA's review of Essure®, it was the **STOP 01** and **STOP 06** studies that were used to support the feasibility and mechanism of action of the Essure® device - "[t]hese studies, which included 99 and 63 patients for perihysterectomy and pre-hysterectomy studies, respectively, yielded data on device placement, patient comfort, as well as histological data to support the mechanism of action of the device."[5]

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[2] During the pre-market stages of Essure®, the device was named and/or referred to as the "STOP Device."

[3] *See* ESSURE System for Permanent Birth Control Executive Summary, available at: https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM463460.pdf.

[4] *See* Dr. Gimpelson's CV, available at: http://webcache.googleusercontent.com/search?q=cache:kgzZ492SnLkJ:www.mdnetlink.com/gimpelson/rjgvitae.doc+&cd=4&hl=en&ct=clnk&gl=es.

[5] *See* "FDA Review Document: Review of the Essure System for Hysteroscopic Sterilization," prepared for the September 24, 2014 meeting of the Obstetrics and Gynecology Devices Advisory Panel, available at: https://www.fda.gov/downloads/AdvisoryCommittees/UCM463486.pdf.

E. With respect to the Pivotal Study, Conceptus contracted with Dr. David Levine at St. Luke's Hospital in Chesterfield, Missouri to be the principal investigator.[6] The purpose of the Pivotal Trial was to demonstrate the safety and effectiveness of the [Essure®] device in providing permanent contraception.[7] Chesterfield, Missouri is ***one of only eight*** principal sites in the United States to perform the Pivotal Trial.[8] That Pivotal Trial took place between May 2000 and February 2001 in Missouri, and was ***one of two*** pre-market clinical trials Conceptus was required to perform before Essure® could obtain FDA approval.

F. Conceptus included the results from these clinical studies in its PMA submission to the FDA in April of 2002 and was later granted FDA approval to begin marketing and selling Essure® in November of 2002.[9]

G. The information gained from the Essure® Pivotal Trial also formed the basis for safety and efficacy data in the FDA approved Essure® Instructions for Use ("IFU").[10] At the time of approval, Essure® was Conceptus' ***only*** product, and *Conceptus*

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[6] *See* "Microinsert Nonincisional Hysteroscopic Sterilization", available online at: http://journals.lww.com/greenjournal/Fulltext/2003/07000/Microinsert_Nonincisional_Hysteroscopic.14.aspx.

[7] *See* Essure Professional Labeling (2002) at pp. 12-17, available online at: https://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014c.pdf.

[8] *See* Jay M. Cooper, *et al*., *Microinsert Nonincisional Hysteroscopic Sterilizationn*, 102 ACOG G.J. 59, 59-60 (July 2003), also available online at:

http://journals.lww.com/greenjournal/Fulltext/2003/07000/Microinsert_Nonincisional_Hysteroscopic.14.aspx (last visited Mar. 28, 2017).

[9] *See* Conceptus, Inc. 2002 Form 10-k, available at: https://www.sec.gov/Archives/edgar/data/896778/000095016803001146/d10k.htm.

[10] *See* ESSURE System for Permanent Birth Control Executive Summary, available online at: https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM463460.pdf (last visited Mar. 28, 2017).

chose St. Louis, Missouri as ground zero – it was the first city in the United States to commercially offer the Essure® procedure, which was performed by Dr. Levine.[11]

H. One of the two post-approval studies mandated by the FDA was performed in part in Missouri. The post-approval study performed in part in Missouri – P020014/PAS002 – required that patients from the Pivotal Study be followed for 5 years in order to assess the long-term safety and effectiveness of Essure®.[12] However, Defendants failed to adequately follow-up on the Missouri trial subjects from the P020014/PAS002 study. Had the post-approval study performed in Missouri been adequate and follow-up been competently performed, the true (and highly alarming) safety profile of Essure® would have been made known to Plaintiffs, their physicians, and the public at large, years earlier.

I. The Bayer Defendants also engaged in directed marketing and advertising efforts in St. Louis, Missouri, including direct to consumer and direct to physician marketing. The Bayer Defendants specifically targeted St. Louis, Missouri, as one of eight cities that were part of a broader marketing plan to increase sales and revenue.[13] St. Louis was key to the Bayer Defendants' national marketing plan.

J. Defendants engaged Key Opinion Leaders ("KOL") in Missouri to promote Essure®. For example, Dr. Levine served as a KOL. Dr. Levine was a peer

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[11] *See* "St. Louis women among first to try new birth control procedure", November 15, 2002, available online at: http://www.semissourian.com/story/93623.html.

[12] *See* Regulatory History, available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm; *see also* https://www.ncbi.nlm.nih.gov/pubmed/25917278.

[13] "**We advertise in eight cities** that have been selected based on a hurdle rate penetration of in-office physicians, adequate reimbursement and sales support, and the ability to extrapolate appropriately to predict national results related to various submarket attributes." *See* https://seekingalpha.com/article/106240-conceptus-inc-q3-2008-earnings-call-transcript?page=5 (emphasis added).

reviewer for the articles that positively portrayed Essure®,[14] promoted Essure® in publications,[15] trained other physicians on the procedure,[16] was used in press releases by Conceptus regarding Essure®,[17] and authored a number of white papers discussing the benefits of Essure® as they relate to physician credentialing and re-credentialing.[18]

171. Jurisdiction in this court is proper because the Bayer Defendants have conducted continuous business and research activities that are sufficiently related to the nonresident plaintiffs' suits.

172. Jurisdiction in this court is also proper because the Bayer Defendants and their agents committed torts in whole or in part against Plaintiffs in Missouri, including but not limited to negligent and wrongful conduct in connection with the design, development, testing, promoting, marketing, distribution, labeling and/or sale of Essure®.

173. Further, there is no federal subject matter jurisdiction because no federal question is raised, and there is no diversity jurisdiction.

174. There is no federal diversity jurisdiction, because Plaintiff Janna Laatu and Defendant BAYER CORP. are both citizens of Pennsylvania. Additionally, Plaintiff Heather Henk and Defendant BAYER CORP. are both citizens of Indiana.

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[14] Ballagh, Susan A., "Contraceptive Technology Reports: Sterilization in the Office: The Concept Now is a Reality," February 1, 2003, available online at: https://www.ahcmedia.com/articles/26978-contraceptive-technology-reports-sterilization-in-the-office-the-concept-now-is-a-reality

[15] Levine, David J., "Hysteroscopic Sterilization: a Breakthrough in Women's Health, 2003, available online at: http://www.aagl.org/wp-content/uploads/2013/01/NewsScope_Jan-Mar_20031.pdf.

[16] The Associated Press, November 12, 2002, "St. Louisans try new birth control procedure," available online at: http://www.berkeleydailyplanet.com/issue/2002-11-15/article/16137?headline=St.-Louisans-try-new-birth-control-procedure&status=301.

[17] Conceptus, Inc., "New Data Confirms Successful Use of Essure® Permanent Birth Control," November 9, 2005, available online at: http://www.prnewswire.com/news-releases/new-data-confirms-successful-use-of-essurer-permanent-birth-control-in-an-office-setting-55489802.html.

[18] "Clinical Privilege White Paper: Transcervical sterilization," June, 2006, available online at: http://www.hcpro.com/content/61602.pdf.

175. Likewise, there is no federal diversity jurisdiction because Plaintiff Tymesha Hunt and Defendant BAYER HEALTHCARE LLC are both citizens of Delaware. Additionally, Plaintiff Janna Laatu and Defendant BAYER HEALTHCARE LLC are both citizens of Pennsylvania. Further, there is no federal diversity jurisdiction because Plaintiff Tymesha Hunt and Defendant BAYER ESSURE INC. are both citizens of Delaware. There is also no federal diversity jurisdiction because Plaintiff Tymesha Hunt and Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. are both citizens of Delaware.

176. Venue is proper in this Court, pursuant to § 508.010(4) R.S. Mo., as Plaintiff Laveta Jordan is a citizen of Missouri and is a resident of St. Louis, Missouri and the conduct which gave rise to Plaintiff Laveta Jordan's action occurred in the City of St. Louis, Missouri, as she was first injured in the City of St. Louis, Missouri when she underwent the Essure procedure at the Barnes Jewish Hospital in St. Louis, Missouri.

177. The plaintiffs herein are all properly joined in this action pursuant to 507.040 R.S. Mo as they assert a right to relief under the same series of occurrences and questions of law and fact are common to all plaintiffs in this action.

Respectfully submitted,

Dated: July 13, 2017

/s/ Eric D. Holland
Eric D. Holland (Mo. Bar # 39935)
R. Seth Crompton (Mo. Bar # 57448)
HOLLAND LAW FIRM
300 N. Tucker Blvd., Suite 801
Saint Louis, MO 63101
Tel: (314) 241-8111
Fax: (314) 241-5554
ehollandallfela.com
scrompton@allfela.com

Lewis O. Unglesby (La. Bar #12498)
Lance C. Unglesby (La. Bar #29690)
Adrian M. Simm Jr. (La. Bar #36673)
(Pro Hac Vice Applicants Anticipant)
UNGLESBY + WILLIAMS
607 St. Charles Avenue
New Orleans, Louisiana 70130
Tel: (504) 345-1390

CERTIFICATE OF SERVICE

I hereby certify that on July 13, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all attorneys of record.

Respectfully submitted,

/s/ Eric D. Holland

Eric D. Holland (Mo. Bar # 39935)
Holland Law Firm, LLC
300 N. Tucker Blvd., Suite 801
St. Louis, MO 63101
Tel: 314-241-8111
Fax: 314-241-5554
Email: eholland@allfela.com